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COMMENTS:

Attached are draft amendments and comments for our interview scheduled for tomorrow, Thursday, November 6, 2003 at 11AM Eastern time (9AM Mountain time).

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To: Examiner Hong Liu

From: Susan Doughty

RE: Serial Number 09/777,727 (our docket number 66-99A)

Date: November 4, 2003

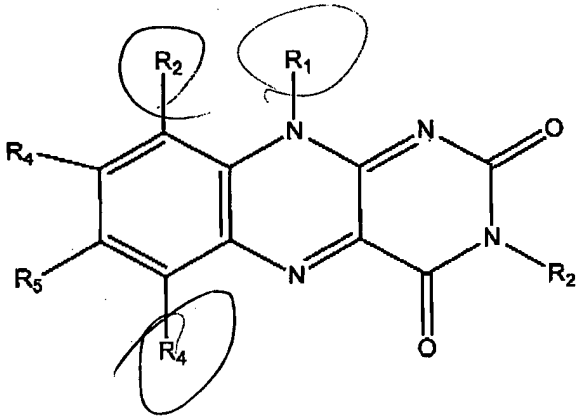
This is a draft outline of arguments for discussion in telephone interview between Susan Doughty and Examiner Hong Liu scheduled for 11am Eastern time (9am Mountain time) Thursday, November 6, 2003. I would like to discuss the 112, first paragraph rejection regarding the term "biologically active protein", the 102(e) rejection over the Goodrich patent and the 103(a) rejections over Spencer and Petering.

Proposed amendment of claim 39 (adds limitation present in specification as filed to expressly exclude compound disclosed in Goodrich in column 5, lines 36-45):

39. A non-toxic composition comprising:

(a) a member selected from the group consisting of biologically active protein, blood, and blood constituents; and

(b) a water soluble blood product additive photosensitizer for inactivating microorganisms suitable for administration to a patient having the structure:



wherein R1, R2, R3, R4, R5 and R6 are, independently from one another, selected from the group consisting of hydrogen; -OH; $-NH_2$; $-SO_4$; $-PO_4$; -Cl; -Br; -I; straight chain or cyclic saccharides with 5 or 6 carbon atoms; ascorbate; amino acid groups; optionally substituted alkyl, alkenyl, alkynyl or aryl groups with from 1 to 20 carbon atoms said alkyl, alkenyl, alkynyl or aryl groups optionally substituted with one or more of -O-, -S-, -OH, -SH, -COH, $-CO_2H$, $-NH_2$, $-SO_4$, $-PO_4$, -F, -Cl, -Br, -I; and $-NR^a-(CR^bR^c)_n-X$ wherein n is an integer from 0 to 20, X is a halogen selected from the group consisting of chlorine, bromine and iodine, R^a, R^b and R^c are, independently of each other, selected from the group consisting of hydrogen; straight chain or

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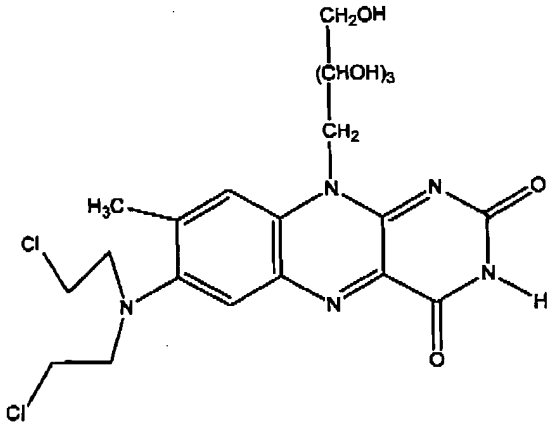
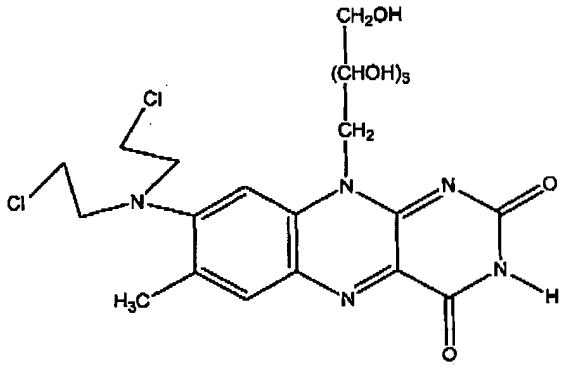
cyclic saccharides with 5 or 6 carbon atoms; ascorbate; amino acid groups; optionally substituted alkyl, alkenyl, alkynyl or aryl groups with from 1 to 20 carbon atoms said alkyl, alkenyl, alkynyl or aryl groups optionally substituted with one or more of -O-, -S-, -OH, -SH, -COH, $-CO_2H$, $-NH_2$, $-SO_4$, $-PO_4$, -F, -Cl, -Br, -I; and salts of the foregoing;

provided that R1, R4, R5 are not all methyl groups when all of R2, R3 and R6 are hydrogens, and provided that R1 is neither H nor -OH nor a straight chain alkyl group where the second carbon of the chain is substituted with -OH or =O except that the compound may be



or



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Rejection under 35 U.S.C. 112, first paragraph

Claims 39-59 were rejected under 35 U.S.C. 112, first paragraph. The Office Action stated: "the claims are not commensurate in scope as to the possibilities for the term 'biologically active protein' in claim 39. The term is open-ended and all encompassing. . . There is no definition in the specification for the term except the mentioning that such a protein can be a therapeutic protein (see page 6). . . Without the disclosure of the nature of the biologically active protein, one having ordinary skill in the art would have to undergo undue experimentation to determine which biologically active protein to use to practice the present invention."

The biologically active protein which is a member of the composition of claim 39 is defined in the specification on page 22, lines 16-19, "The term 'biologically active' means capable of effecting a change in a living organism or component thereof. 'Biologically active' with respect to 'biologically active protein' as referred to herein does not refer to proteins which are part of the microorganisms being neutralized." Proteins which are "capable of effecting a change in a living organism or component thereof" are well known in the art and it would not require any undue experimentation to make and/or use the invention. In addition, the specification states "fluids containing biologically active proteins other than those derived from blood may also be treated by the methods of this invention. Such fluids may also contain one or more components selected from the group consisting of protein, e.g. biologically active protein such as therapeutic protein, blood and blood constituents, without destroying the biological activity of such components" on page 23, lines 2-6. The specification continues on page 23, lines 12-14: "So long as fluid components retain sufficient biological activity to be useful for their intended or natural purposes, their biological activities are not considered to be substantially destroyed." A list of therapeutic protein compositions is given in the specification on page 27, lines 11-18.

Rejection of claims 39-59 under 35 U.S.C. 102(e)

Claims 39-59 were rejected under 35 U.S.C. 102(e) as anticipated by Goodrich (US 6,258,577). The Office Action stated "Goodrich teaches the use of alloxazines such as 7,8,10-trimethylisoalloxazine to inactivate microorganisms in fluids that contain biologically active protein, blood, and blood constituents by mixing the compounds with the material to be decontaminated (see cols. 3-6)."

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In response, the photosensitizers of the present invention are not disclosed in the Goodrich patent. Goodrich discloses photosensitizers "known to the art to be useful for inactivating microorganisms" as useful in the invention in column 4, lines 47-49. The present invention includes photosensitizers "except those previously known to the art" (page 11, lines 19-20).

Also, the compounds listed in Goodrich (column 5 and 6) are not included in the present invention. Only the first and third compounds shown in column 5 have the backbone of the photosensitizer shown in claim 39. The first compound shown in column 5 is expressly excluded by the limitation in claim 39 "provided that R1 is neither H not –OH nor a straight chain alkyl group where the second carbon of the chain in substituted with –OH or =O." The third compound shown in column 5 of the Goodrich patent is excluded by the new limitation in claim 39. This limitation is supported by the specification as filed on page 10, line 16.

Rejection of claims 39-59 under 35 U.S.C. 103(a) over Spencer and Petering

Claims 39-59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer and Petering. The Office Action stated: "the term 'blood constituents' reads on water. For this reason, the amended composition claim is not blood-product specific and the composition of the present invention is patently indistinguishable from the composition in the reference, which is composed of water and the isoalloxazine compound."

It is noted that in response to the agreement in the interview dated January 28, 2003, the claims were amended to composition claims comprising (a) a member selected from the group consisting of biologically active protein, blood, and blood constituents; and
(b) a water soluble blood product additive photosensitizer. Neither Spencer nor Petering discuss a water soluble photosensitizer, so the composition claimed is neither anticipated nor made obvious by Spencer or Petering. In addition, it is not seen where Spencer or Petering discuss a composition comprising an isoalloxazine and water. Further guidance from the Examiner is requested regarding the location in Spencer of disclosure relating to "water and the isoalloxazine compound."

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In addition, the term "blood constituents" is described in the specification on page 27, lines 8-11. "Examples of materials which may be treated by the methods of this invention are whole blood and aqueous compositions containing biologically active proteins derived from blood or blood constituents. Packed red cells, platelets, and plasma (fresh or fresh frozen plasma) are exemplary of such blood constituents." The meaning of "blood constituents" as defined in the specification does not include water.

Rejection of claims 39-59 under 35 U.S.C. 103(a) over Goodrich

Claims 39-59 were rejected under 35 U.S.C. 103(a) over Goodrich (US 6,258,577). Both the subject application and the Goodrich patent are commonly owned, therefore, 103(c) applies and the rejection is moot.

Susan Doughty

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